TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330
PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

SUBPART B: PHARMACY TECHNICIAN

SUBPART C: PHARMACIST

SUBPART D: PHARMACY LICENSURE

AUTHORITY: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].

SOURCE: Rules and Regulations Promulgated for the Administration of the Illinois Pharmacy Practice Act, effective August 20, 1975; amended March 8, 1977; amended at 4 Ill. Reg. 1234, effective July 11, 1980; amended at 5 Ill. Reg. 2997, effective March 11, 1981; codified at 5 Ill. Reg. 11049; emergency amendment at 6 Ill. Reg. 916, effective January 6, 1982, for a maximum of 150 days; amended at 6 Ill. Reg. 7448, effective June 15, 1982; amended at 7 Ill. Reg. 6496, effective June 30, 1983; amended at 9 Ill. Reg. 16918, effective October 23, 1985; amended at 10 Ill. Reg. 21913, effective December 17, 1986; transferred from Chapter I, 68 Ill. Adm. Code 330 (Department of Registration and Education) to Chapter VII, 68 Ill. Adm. Code 1330 (Department of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at 12 Ill. Reg. 2957; amended at 12 Ill. Reg. 17394, effective October 14, 1988; amended at 16 Ill. Reg. 19811, effective December 7, 1992; amended at 21 Ill. Reg. 12600, effective August 29, 1997; amended at 22 Ill. Reg. 21959, effective December 1, 1998; amended at 23 Ill. Reg. 14131, effective November 18, 1999; amended at 24 Ill. Reg. 8548, effective June 9, 2000; amended at 26 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389, effective December 11, 2003; emergency amendment at 29 Ill. Reg. 5586, effective April 1, 2005, for a maximum of 150 days; amended at 29 Ill. Reg. 13639, effective August 25, 2005; amended at 30 Ill. Reg. 14267, effective August 21, 2006; amended at 30 Ill. Reg. 16930, effective October 12, 2006; emergency amendment at 31 Ill. Reg. 16045, effective November 19, 2007, for a maximum of 150 days; amended at 32 Ill. Reg. 3262, effective February 21, 2008; amended at 32 Ill. Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill. Reg. 6688, effective April 29, 2010; new Part adopted at 34 Ill. Reg. 6690, effective April 29, 2010; amended at 39 Ill. Reg. 6267, effective April 23, 2015; amended at 41 Ill. Reg. 10643, effective August 18, 2017; amended at 42 Ill. Reg. 20022, effective November 9, 2018; amended at 47 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 1330.20 Fees

The following fees are not refundable:

a) Registration as a Pharmacy Technician, Student Pharmacist or Certified Pharmacy Technician

1) The fee for application for a certificate of registration as a pharmacy technician or certified pharmacy technician is $40.

2) The fee for the renewal of a certificate of registration as a pharmacy technician, student pharmacist or certified pharmacy technician shall be calculated at the rate of $25 per year.

b) License as a Pharmacist

1) The fee for application for a license as a pharmacist is $75.

2) In addition, applicants for any examination as a registered pharmacist shall be required to pay, either to the Division or to the designated testing service, a fee covering the cost of determining an applicant's eligibility and providing the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the applicant's application for examination has been received and acknowledged by the Division or the designated testing service, shall result in the forfeiture of the examination fee.

3) The fee for a license as a registered pharmacist, registered or licensed under the laws of another state or territory of the United States, is $200.

4) The fee for the renewal of a license shall be calculated at the rate of $75 per year.

5) The fee for the restoration of a license other than from inactive status is $50 plus all lapsed renewal fees, not to exceed $450.

6) Applicants for the preliminary diagnostic examination shall be required to pay, either to the Division or to the designated testing service, a fee covering the cost of determining an applicant's eligibility and providing the examination. Failure to appear for the examination on the scheduled date, at the time and place specified, after the application for examination has been received and acknowledged by the Division or the designated testing service, shall result in the forfeiture of the examination fee.

~~7)~~ ~~The fee to have the scoring of an examination authorized by the Division reviewed and verified is $20 plus any fee charged by the applicable testing service.~~

c) License as a Pharmacy

1) The fee for application for a license for a pharmacy under the Act is $100.

2) The fee for the renewal of a license for a pharmacy under the Act shall be calculated at the rate of $100 per year.

3) The fee for the change of a pharmacist-in-charge is $25.

d) General Fees

1) The fee ~~for the issuance of a duplicate license, for the issuance of a replacement license for a license that has been lost or destroyed or~~ for the issuance of a license with a change of name or address other than during the renewal period is $20. No fee is required for name and address changes on Division records when no duplicate certification is issued.

2) The fee for a certification of a registrant's record for any purpose is $20.

3) The fee to have the scoring of an examination administered by the Division reviewed and verified is $20.

~~4) The fee for a wall certificate showing licensure or registration shall be the actual cost of producing the certificate.~~

~~5) The fee for a roster of persons registered as pharmacists or registered pharmacies in this State shall be the actual cost of producing the roster.~~

~~6) The fee for pharmacy licensing, disciplinary or investigative records obtained pursuant to a subpoena is $1 per page.~~

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.50 Vaccinations/Immunizations

a) Qualifications

1) A pharmacist, or a student pharmacist or a pharmacy technician under the direct supervision of a pharmacist, may administer vaccinations/immunizations to persons who are 7~~14~~ years of age or older pursuant to a valid patient specific prescription or a standing order by a physician licensed to practice medicine in all of its branches under the Medical Practice Act of 1987 [225 ILCS 60].

~~2) A pharmacist, or student pharmacist under the direct supervision of a pharmacist, may administer influenza (inactivated influenza vaccine and live attenuated influenza intranasal vaccine) and Tdap (tetanus, diphtheria,~~

~~acellular pertussis) vaccines/immunizations to persons who are 10 to 13 years of age pursuant to a valid patient specific prescription or a standing order by a physician licensed to practice medicine in all of its branches under the Medical Practice Act of 1987.~~

2~~3~~) The pharmacist, student pharmacist, or pharmacy technician shall successfully complete a course of training accredited by the Accreditation Council on Pharmacy Education, or a similar health authority or professional body approved by the Division. The pharmacist who is responsible for supervising the pharmacy student or pharmacy technician has the sole responsibility of evaluating the appropriateness of each vaccination prior to its administration and maintains full responsibility and oversight of the process.

3~~4~~) The pharmacist shall maintain a current Basic Life Support Certification for Healthcare Providers issued by the American Heart Association, the American Red Cross, the American Safety and Health Institute, or an equivalent as determined by the Division.

4~~5~~) Each pharmacy, or pharmacist functioning outside of a pharmacy, shall have available a current copy or electronic version of the CDC reference "Epidemiology and Prevention of Vaccine – Preventable Diseases" at the location where vaccinations are administered.

5~~6~~) The administration of vaccines shall be done by a pharmacist, or a student pharmacist or pharmacy technician under the direct supervision of a pharmacist, who has completed training as described in this section.

b) Protocols, Policies and Procedures

1) Prior to administrating vaccinations/immunizations, a pharmacist, or a student pharmacist or a pharmacy technician under the direct supervision of a pharmacist, must follow protocols written by a physician licensed to practice medicine in all of its branches for the administration of vaccines and treatment of severe adverse events following administration of vaccines.

2) The pharmacy must maintain written policies and procedures for handling and disposal of all used supplies or contaminated equipment.

3) The pharmacist, or student pharmacist under the direct supervision of a pharmacist, must give the appropriate vaccine information statement (VIS) to the patient or legal representative prior to each vaccination. The

pharmacist, or student pharmacist under the direct supervision of a pharmacist, must ensure that the adult patient or minor (age 710 ~~for influenza and Tdap, age 14 and older for all other vaccines~~) patient's parent or legal representative is available and has the vaccine information statement.

4) The pharmacy must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider named by the patient.

c) Recordkeeping and Reporting

1) All records regarding each administration of a vaccine must be kept for 5 years. These records shall include:

A) The name, address and date of birth of the patient.

B) Date of administration and site of injection of the vaccine.

C) Name, dose, manufacturer, lot number and beyond use date of the vaccine.

D) Name and address of the patient's primary health care provider named by the patient.

E) The name or unique identifier of the administering pharmacist.

F) Which vaccine information statement (VIS) was provided.

2) A pharmacist who administers or oversees the administration of any vaccine must ensure that the report of that administration, is made ~~within 30 days after the date of administration,~~ to the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE) or to the ~~patient's~~ primary healthcare provider named by the patient within 30 days of administration.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.90 Restoration of a Pharmacist License

a) A pharmacist seeking restoration of a certificate of registration that has expired for 5 years or less shall have the license restored upon payment of all lapsed renewal fees required by Section 1330.20 and proof of 30 hours of CE ~~continuing~~

~~education~~ (e.g., certificate of attendance or completion) in accordance with Section 1330.100.

b) A pharmacist seeking restoration of a certificate of registration that has been placed on inactive status for 5 years or less shall have the license restored upon payment of the current renewal fee and proof of 30 hours of CE ~~continuing education~~ (e.g., certificate of attendance or completion) in accordance with Section 1330.100.

c) A pharmacist seeking restoration of a certificate of registration after it has expired or been placed on inactive status for more than 5 years shall file an application, on forms supplied by the Division, together with the fee required by Section 1330.20 and proof of 30 hours of CE ~~continuing education~~ (e.g., certificate of attendance or completion) in accordance with Section1330.100.

1) The pharmacist shall also submit either:

A) Certification of active practice in another jurisdiction. Evidence shall include a statement from the appropriate board or licensing authority in the other jurisdiction that the registrant was authorized to practice during the term of active practice; or

B) An affidavit attesting to military service as specified in Section 12 of the Act. The applicant restoring a license shall be excused from the payment of any lapsed fee or any restoration fees.

2) A pharmacist who is unable to submit proof of satisfaction of either subsection (c)(1)(A) or (B) shall submit proof of completion of:

A) 30 hours of CE~~continuing education~~; and

B) Either:

i) 600 hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to restoration; or

ii) Successful completion of the North American Pharmacist Licensure Examination (NAPLEX)~~Pharmacist Assessment for Remediation Evaluation (PARE) examination~~. To be successful, an applicant must receive a passing score of 75 on the NAPLEX~~an overall score of 80 or higher, as well as~~

~~a minimum score of 75 in each of the 3 content areas on the PARE examination~~.

3) The course work or clinical training described in subsections (c)(2)(A) and (c)(2)(B)(i) must have the prior approval of the Board.

d) When the accuracy of any submitted documentation, or the relevance or sufficiency of the course work or experience, is questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be requested to:

1) Provide information as may be necessary; and/or

2) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given, or clear up any discrepancies in information.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.100 Continuing Education ("CE")

a) CE~~Continuing Education~~ Requirements

1) Each person who applies for renewal of a license as a pharmacist shall complete 30 hours of ~~continuing education (~~CE~~)~~ during the 24 months preceding the expiration date of the license, in accordance with Section 12 of the Act.

2) A renewal applicant is not required to comply with CE requirements for the first renewal after original licensure.

b) Approved CE~~Continuing Education~~

1) CE credit shall be based upon the completion of courses offered by providers approved by the Accreditation Council for Pharmacy Education. These courses may be completed outside the State of Illinois.

2) Undergraduate Coursework

A) Undergraduate coursework taken after completion of a first professional degree in pharmacy through a recognized college or approved school of pharmacy (in accordance with Section 1330.300~~ of this Part~~) may be used to fulfill the CE requirement if:

i) Evidence of course completion through an official transcript and other documentation (e.g., certificate of completion or degree) of the university or college is submitted that indicates the number of course content hours completed; and

ii) These courses are completed for college credit.

B) CE credit will be earned for each undergraduate course completed. One semester hour is equivalent to 15 CE~~continuing education~~ hours, and one quarter hour is equivalent to 10 CE~~continuing education~~ hours.

c) Certification of CE Requirements

1) Each renewal applicant shall certify on the renewal application full compliance with CE requirements set forth in subsection (a).

2) The Division may require additional evidence demonstrating compliance with the CE requirements. It is the responsibility of each renewal applicant to retain or otherwise produce evidence of the compliance (e.g., certificate of attendance or completion). Evidence shall be required in the context of the Division's random audit in accordance with Section 12 of the Act.

d) The same CE hours cannot be used to fulfill the CE requirement for more than one renewal period.

e) Waiver of CE Requirements

1) Any renewal applicant seeking renewal of a license without having fully complied with these CE requirements shall file with the Division a renewal application, along with the required fee, a statement setting forth the facts concerning noncompliance and a request for waiver of the CE requirements on the basis of these facts. A request for waiver shall be made prior to the renewal date. If the Division, upon the written recommendation of the Board, finds from the affidavit or any other evidence submitted that good cause has been shown for granting a waiver, the Division shall waive enforcement of the CE requirements for the renewal period for which the applicant has applied.

2) Good cause shall be defined as an inability to fulfill the CE requirements

during the applicable period because of:

A) Full-time service in the armed forces of the United States of America during the applicable period; or

B) Extreme hardship, which shall be determined on an individual basis by the Board and shall be limited to documentation of:

i) An incapacitating illness, documented by a currently licensed physician; or

ii) Physical inability to travel to the sites of approved programs, as documented by a currently licensed physician; or

iii) Any other similar extenuating circumstances (e.g., illness of family member).

3) An interview before the Board with respect to a request for waiver may~~shall~~ be granted ~~only~~ if the interview is requested at the time the request for the waiver is filed with the Division. The renewal applicant requesting a waiver shall be given at least 20 days written notice of the date, time and place of the interview by ~~certified~~ mail, or email~~return receipt requested~~.

4) Any renewal applicant who submits a request for waiver pursuant to subsection (e)(1) shall be deemed to be in good standing until the final Division decision on the application has been made.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART B: PHARMACY TECHNICIAN

Section 1330.230 Continuing Education ("CE") for Certified Pharmacy Technicians

a) CE Requirements

1) Number of Hours of CE Required

A) Each person who applies for renewal of a license as a certified pharmacy technician shall complete 10 hours of CE during the 12 months preceding the expiration date of the license, in accordance with Section 9.5 of the Act.

B) A renewal applicant is not required to comply with CE requirements for the first renewal after original licensure.

2) Required Topics for CE

A) At least one hour of continuing pharmacy education must be on the subject of pharmacy laws, pharmacy rules and ethics;

B) At least one hour of continuing pharmacy education must be on the subject of patient safety; and

C) Any other applicable CE requirement per 68 Ill. Adm. Code 1130.

b) Approved CE

1) The completion of courses offered by providers approved by the Accreditation Council on Pharmacy Education or another standardized nationally approved education program approved by the Department, which may be completed outside the State of Illinois.

2) The pharmacist-in-charge and the certified pharmacy technician must maintain records showing proof of training that constituted the pharmacy technician's CE.

c) Certification of CE Requirements

1) Each renewal applicant shall certify on the renewal application full compliance with CE requirements set forth in this Part.

2) The Division may require additional evidence demonstrating compliance with the CE requirements. It is the responsibility of each renewal applicant to retain or otherwise produce evidence of the compliance (e.g., certificate of attendance or completion). Evidence shall be required in the context of the Division's random audit in accordance with Section 9.5 of the Act.

d) The same CE hours cannot be used to fulfill the CE requirement for more than one renewal period.

e) Waiver of CE Requirements

1) Any renewal applicant seeking to renew their license without having fully complied with these CE requirements shall file with the Division a

renewal application, along with the required fee, a statement setting forth the facts concerning noncompliance and a request for waiver of the CE requirements with facts explaining the basis of the request. A request for waiver shall be made prior to the renewal date. If the Division, upon the written recommendation of the Board, finds from the affidavit or any other evidence submitted that good cause has been shown for granting a waiver, the Division shall waive enforcement of the CE requirements for the renewal period for which the applicant has applied.

2) Good cause shall be defined as an inability to fulfill the CE requirements during the applicable period because of:

A) Full-time service in the armed forces of the United States of America during the applicable period; or

B) Extreme hardship, which shall be determined on an individual basis by the Board and shall be limited to documentation of:

i) An incapacitating illness, documented by a currently licensed physician;

ii) Physical inability to travel to the sites of approved programs, as documented by a currently licensed physician; or

iii) Any other similar extenuating circumstances (e.g., illness of a family member).

3) An interview before the Board may be granted with respect to a request for waiver if the interview is requested at the time the request for the waiver is filed with the Division, and the Board determines that an interview will be necessary to consider the waiver request. The renewal applicant requesting a waiver shall be given at least 20 days written notice of the date, time, and place of the interview by mail or email.

4) Any renewal applicant who submits a request for waiver pursuant to subsection (e)(1) shall be deemed to be in good standing until the final Division decision on the application has been made.

(Source: Added at 47 Ill. Reg. _____, effective _____)

SUBPART C: PHARMACIST

Section 1330.360 Pharmacy Residents

A pharmacy resident participating in a nationally accredited residency program is exempt from Section 15.1(a) of the Act to the extent the provision conflicts with the requirements of the nationally accredited residency program.

(Source: Added at 47 Ill. Reg. _____, effective _____)

SUBPART E: TYPES OF PHARMACIES

Section 1330.500 Community Pharmacy Services

a) Pharmacies that engage in general or specialty community pharmacy practice and are open to, or offer pharmacy service to, the general public shall, in addition to any other requirements of the Act and this Part, comply with this Section. A community pharmacy that, in addition to offering pharmacy services to the general public, provides institutional services shall also comply with Section 1330.520.

b) Staffing of the Pharmacy

1) Whenever the hours of the pharmacy differ from those of the establishment in which the pharmacy is located, the schedule during which pharmacy services are provided shall be conspicuously displayed.

2) Whenever a pharmacy is open and a pharmacist is not present and available to provide pharmacy services, a sign stating that situation shall be conspicuously displayed.

3) No prescription may be dispensed when a pharmacist is not physically present in the establishment ~~and on duty~~.

c) Recordkeeping Requirements for Dispensing Prescription Drugs

1) For every prescription dispensed, the prescription record shall contain the name, initials or other unique identifier of the pharmacist who dispenses the prescription drugs. No prescription may be dispensed after 15 months~~one year~~ from the date of the original issuance of the prescription by the prescriber.

2) Whenever a prescription is dispensed by a registered pharmacy technician or certified pharmacy technician under the supervision of a pharmacist, the prescription record shall contain the names, initials or other unique

identifier of both the supervising pharmacist and the registered pharmacy technician or certified pharmacy technician who dispenses the prescription.

3) Refilling a Prescription

A) Each refilling of a prescription shall be entered on the prescription or on another appropriate, uniformly maintained, readily retrievable record that indicates, by the number of the prescription, the following information:

i) The name and dosage form of the drug;

ii) The date of each refilling;

iii) The quantity dispensed;

iv) The name or initials of the pharmacist and the pharmacy technician, if applicable, in each refilling; and

v) The total number of refills remaining for the prescription.

B) If the pharmacist does not otherwise indicate in a uniformly maintained record, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.

4) Presentation of a written prescription copy or prescription label shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of the copy or prescription label shall contact the prescribing practitioner to obtain a new prescription order.

5) Copies of prescriptions given to an ultimate consumer shall be marked "For Information Purposes Only".

6) Subject to Section 18 of the Act, any information required to be kept pursuant to this Section may be recorded and stored in a computerized pharmaceutical information system that meets the standards of performance stated in the regulations of the Drug Enforcement Administration (21 CFR 1306; 2014), except as provided in subsection (c)(7), and shall include the capability to:

A) Retrieve the original prescription order information for those prescription orders currently authorized for refilling;

B) Retrieve the current prescription orders, including, at a minimum, name of drug, date of refill, quantity dispensed, name and identification code of the manufacturer in the case of a generically written prescription or a generic interchange, name or initials of the dispensing pharmacist and technician for each refill, and the total number of refills dispensed to date;

C) Supply documentation of refill information entered by the pharmacist using the system through a hard copy printout of each day's refill data that has been verified for correctness. This printout must include for each prescription filled at least the following information:

i) The name and dosage form of the drug;

ii) The date of each refilling;

iii) The quantity dispensed;

iv) The name or initials of the pharmacist in each refilling and the pharmacy technician, if applicable;

v) The patient's name;

vi) The prescriber's name; and

vii) The prescription number for the prescription.

7) In lieu of the printout required by subsection (c)(6), the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in the dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

8) All refill data shall be maintained by the pharmacy on the premises for 5 years, in accordance with Section 18 of the Act. The pharmacy shall have the appropriate equipment on the premises to provide readily retrievable

information in the course of an on-site inspection. A hard copy printout shall be provided to the Division, upon request, within 48 hours.

d) Any drug that is dispensed pursuant to prescription, other than vaccinations administered in the pharmacy, shall have affixed to its container a label as provided in Section 22 of the Act.

e) No person shall establish or move to a new location any pharmacy unless the pharmacy is licensed with the Division and has on file with the Division a verified statement that:

1) The pharmacy is or will be engaged in the practice of pharmacy; and

2) The pharmacy will have in stock and will maintain sufficient prescription drugs and materials to protect the public it serves within 30 days after opening of the pharmacy.

f) Pharmacies have a duty to deliver lawfully prescribed drugs to patients and to distribute nonprescription drugs approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or to substitute a generic drug as permitted in Section 25 of the Act in a timely manner, or to contact the prescriber to obtain authorization to dispense a different drug that produces a similar clinical effect in a timely manner, except for the following or substantially similar circumstances:

1) When, in the pharmacist's professional judgment, after screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including, but not limited to, serious interactions with nonprescription or over-the-counter drugs), drug-food interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, or clinical abuse or misuse, pursuant to Section 3(aa) of the Act, she or he determines that the drug should not be dispensed due to one of the foregoing clinical reasons;

2) National or State emergencies or guidelines affecting availability, usage or supplies of drugs;

3) Lack of specialized equipment or expertise needed to safely produce, store or dispense drugs, such as certain drug compounding or storage for nuclear medicine;

4) Potentially fraudulent prescriptions;

5) Unavailability of drug; or

6) The drug is not typically carried in similar practice settings in the State.

g) Nothing in this Section requires pharmacies to dispense a drug without payment of their usual and customary or contracted charge.

h) All pharmacies shall be required to maintain the following current resource materials, either in hard copy or electronic format:

1) Copies of the Act and this Part;

2) The Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;

3) 21 CFR (Food and Drugs; 2014); and

4) The Illinois Hypodermic Syringes and Needles Act [720 ILCS 635].

i) If the lawfully prescribed drug or nonprescription drug approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies is not in stock or is otherwise unavailable, or the prescription cannot be filled pursuant to subsection (f)(1) or (f)(6), the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy that, consistent with customary pharmacy practice, may include obtaining the drug. These alternatives include but are not limited to:

1) Contact the prescriber to address concerns such as those identified in subsection (f)(1);

2) If requested by the patient or his or her agent, return unfilled lawful prescriptions to the patient or agent; or

3) If requested by the patient or his or her agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner.

j) Any mail order pharmacy that provides services in Illinois shall provide, during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, a toll-free telephone service to facilitate communication between patients in this State and a pharmacist retained by the mail order pharmacy who has access to the patient's records. The toll free number must be disclosed on the label affixed to each container of drugs dispensed to residents of the State.

k) Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions:

1) Intentionally destroying unfilled lawful prescriptions;

2) Refusing to return unfilled lawful prescriptions;

3) Violating a patient's privacy;

4) Discriminating against patients or their agents in a manner prohibited by State or federal laws;

5) Intimidating or harassing a patient; or

6) Failing to comply with the requirements of this Section.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.510 Telepharmacy

a) Telepharmacy shall be limited to the types of operations described in this Section. Each site where such operations occur shall be a separately licensed pharmacy. Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that the dispensing pharmacist and the pharmacist-in-charge shall not be required to be licensed in Illinois, except as otherwise provided in this Part.

b) Remote Dispensing Site

1) Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site. ~~Unless otherwise provided by federal law, all written prescriptions shall be delivered to the home pharmacy for filing within 72 hours.~~ Records shall be maintained at the remote dispensing site~~the home pharmacy in files separate from the home pharmacy files~~.

2) A remote site is considered to be under the supervision of the pharmacist-in-charge of the home pharmacy. Each home pharmacy may supervise no more than 3 remote sites that are simultaneously open.

3) The remote site shall use its home pharmacy and pharmacy management system.

A) The system shall assign consecutive prescription numbers.

~~B)~~ ~~All records must be maintained at the home pharmacy.~~

B~~C~~) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.

C~~D~~) Daily reports must be separated for the home and remote site.

4) A pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.

A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.

C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.

D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.

5) Counseling must be done by a pharmacist via video link and audio link ~~before the drug or medical device is released~~. pursuant to Section 700 The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

6) A pharmacist-in-charge or his or her designated pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available on site for pharmacy investigator inspection.

7) Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored ~~at the home pharmacy and~~ at the remote site.

8) There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site.

A) The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist.

B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy.

C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.

9) The facility must have a sign clearly identifying it as a remote dispensing site.

~~10)~~ ~~Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.~~

10~~11~~) The facility shall have an area for patient consultation, exclusive of any waiting area.

c) Remote Consultation Site

1) These sites have no prescription inventory.

2) Only filled prescriptions, filled at the home pharmacy, with final patient labeling attached are allowed at these sites.

3) These sites must be staffed with a pharmacy technician or certified pharmacy technician who has the knowledge necessary to use computer audio/video link for dispensing and consultation to occur. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

4) Written prescriptions may be received at a remote consultation site. All written prescriptions presented at a remote consultation site shall be delivered to the home pharmacy within 72 hours.

5) Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.

6) Recordkeeping shall be conducted by the pharmacist (time/date) when dispensing and counseling occurred.

7) The facility shall have a room for patient consultation exclusive of any waiting area.

8) The facility must have a sign clearly identifying it as a remote consultation site.

d) Automated Pharmacy Systems (Section 22(b) of the Act)

1) Remote Automated Pharmacy Systems (RAPS)

A) These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.

B) These systems shall have prescription inventory, which must be secured in an automated pharmacy system and electronically connected to and controlled by the home pharmacy.

C) A pharmacist must approve all the prescription orders before they are released from the RAPS.

D) Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.

E) All filled prescriptions~~prescription~~ must have a label that meets the requirements of the Act attached to the final drug container.

F) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.

G) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.

H) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:

i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.

ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.

iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.

I) Written prescriptions may be received at a~~an~~ RAPS. All written prescriptions presented to a~~an~~ RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.

2) Kiosk

A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.

B) A home pharmacy may only use the kiosk with prior approval of a patient.

C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.

D) A kiosk shall:

i) When located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy;

ii) When not located on the same premises or campus as the pharmacy, inform a patient, if he is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;

iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined

that he or she desires to counsel the patient in person regarding the prescription.

3) A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device:

A) Is secured against a wall or floor;

B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;

C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;

D) Records the time and date that the patient removed the prescription from the system.

4) A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system licensed pursuant to this Section.

e) All pharmacists performing services in support of a remote dispensing site, remote consultation site, kiosk, or RAPS must display a copy or electronic image of their licenses at the remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois.

f) Each remote site must display a sign, easily viewable by the customer, that states:

1) The facility is a telepharmacy supervised by a pharmacist located at (address); and

2) The pharmacist is required to talk to you, over an audio/visual link, each time you pick up a prescription.

g) No remote site may be open when the home pharmacy is closed, unless a pharmacist employed or contracted by the home pharmacy, or by a pharmacy

contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.520 Offsite Institutional Pharmacy Services

a) Pharmacies that are not located in the facilities they serve and whose primary purpose is to provide services to patients or residents of facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, ~~or~~ the University of Illinois Hospital Act, or the Illinois Department of Human Services, Division of Substance Use Prevention and Recovery shall, in addition to any other requirements of the Act and this Part, comply with this Section.

b) Recordkeeping Requirements for Dispensing Prescriptions or Orders

1) Every prescription or order dispensed shall be documented with the name, initials or other unique identifiers of the pharmacist (and pharmacy technician if one is used) authorized to practice pharmacy under the provisions of the Act who dispenses the prescription or order. For purposes of the Act, an authorized person is:

A) A pharmacist licensed in the State of Illinois; or

B) A ~~registered~~ pharmacy technician, certified pharmacy technician or student pharmacist under the supervision of a pharmacist.

2) Each pharmacy must maintain records for 5 years that contains the information in subsection (b)(3). This information shall be readily retrievable and in a format that provides enforcement agents a concise, accurate and comprehensive method of monitoring drug distribution via an audit trail. This system may require 2 or more documents that, when read together, will provide all the information required by federal (e.g., the regulations of the Drug Enforcement Administration (21 CFR 1300 et seq.; 2014)) and State (e.g., the Pharmacy Practice Act and the Illinois Controlled Substances Act [720 ILCS 570]) statute.

3) In addition to the recordkeeping requirements of subsection (b)(2), a uniformly maintained, readily retrievable hard copy record or back-up documentation of each prescription or order dispensed shall be maintained by the pharmacy for 5 years and shall include:

A) Name of resident;

B) Date of order;

C) Name, strength and dosage form of drug, or description of the medical device ordered;

D) Quantity dispensed (a separate record should be maintained when the quantity billed differs from the quantity dispensed, e.g., unit dose transfer systems);

E) Directions for use;

F) Quantity billed;

G) Prescriber's name;

H) Prescriber's signature and/or DEA number when required for controlled substances; and

I) The drug name and identification code or the manufacturer in case of a generically ordered medication or a generic interchange.

4) No prescription may be filled or refilled for a period in excess of 15 months~~one year~~ from the date of the original issuance of the prescription or order by the prescriber.

5) Subject to Section 18 of the Act, any information required to be kept pursuant to this Section may be recorded and stored in a:

A) computerized pharmaceutical information system that meets the standards of performance required by the regulations of the Drug Enforcement Administration (21 CFR 1306; 2014) and shall include the capability to:

i) Retrieve the original medication order information for those medication orders that are currently authorized;

ii) Retrieve the current history of medication orders that shall, at a minimum, include the name of drug, the date of filling, the quantity dispensed, the name and identification code of manufacturer in the case of a generically written prescription or a generic interchange, for each filling, and the total number of refills when read in conjunction with

any off-line hard copy of the history of medication orders dispensed to date; and

iii) Supply documentation of the correctness of filling information entered into a system must be provided by the pharmacist using the system by way of a hard copy printout of each day's filling data that has been verified, dated and signed by the dispensing pharmacist; or

B) bound logbook~~log book~~, or separate file, in which each individual pharmacist involved in dispensing shall sign a statement each day attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

c) In the event the long-term~~long term~~ care facility changes pharmacy provider services, their new provider must obtain the orders from the long-term~~long term~~ care facility and verify the authenticity and accuracy of the orders with the prescriber.

d) Staffing of the Pharmacy. When the pharmacy is closed, the public and any employees not registered under the Act are to be prohibited access to the filling and dispensing area.

e) Labeling Requirements

1) Medications for Future Use

A) Parenteral solutions to which a drug or diluent has been added or that are not in their original manufacturer's packaging shall contain the following information on the outer label:

i) Name, concentration and volume of the base parenteral solution;

ii) Name and strength of drugs added;

iii) Beyond use date and date of the admixture. Beyond use date, unless otherwise specified in the individual compendia monograph shall be not later than the beyond

use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

iv) Reference code to identify source and lot number of drugs added.

B) Non-parenterals repackaged for future use shall be identified with the following information:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged, whichever is earlier; and

iv) Reference code to identify source and lot number.

2) Medications Prepared for Immediate Use

A) All medications prepared by the pharmacy for immediate dispensing to a specific resident or patient in the facility shall be dispensed in a container identified with:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Dispensing date;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Quantity dispensed;

vi) Directions for use;

vii) Prescriber's name; and

viii) Beyond use date if less than 60 days from date of dispensing.

B) Pharmacies dispensing medications to a specific resident or patient in the facility via unit dose shall label each order with the following information:

i) Name of the resident;

ii) Resident's room and bed number;

iii) Date of order;

iv) Name, strength and dosage form of drug, or description of the medical device ordered;

v) Directions for use; and

vi) Prescriber's name.

f) Pharmacies that compound and dispense sterile products shall comply with Section 1330.640.

g) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:

1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, the name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.

2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel or persons authorized to administer medication pursuant to a valid physician's order of a physician licensed to practice medicine in all of its branches in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at that time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.

3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the physician's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.530 Onsite Institutional Pharmacy Services

a) Onsite Pharmacies~~Pharmacies located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients,~~

~~employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.~~

1) A pharmacy located in facilities licensed under the Nursing Home Care Act, the Hospital Licensing Act, or the University of Illinois Hospital Act, or that are operated by the Department of Human Services or the Department of Corrections, and that provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.

2) A pharmacy that is not located in the facilities it serves and the facilities it serves are licensed under the Illinois Department of Human Services, Division of Substance Use Prevention and Recovery, for the prevention, intervention, treatment, and recovery support of substance use disorders or for the treatment of mental health.

b) Recordkeeping Requirements

1) Every prescription or medication order filled or refilled shall contain the name, initials or other unique identifier of the pharmacist (and pharmacy technician if one is used) who fills or refills the prescription or medication order, or the name, initials or other unique identifier may be recorded on another appropriate, uniformly maintained and readily retrievable record that indicates, at least, the following information:

A) The name and dosage form of the drug;

B) The date of filling or refilling; and

C) The quantity dispensed.

2) No prescription may be dispensed for a period in excess of 15 months~~one year~~ from the date of the original issuance of the prescription by the prescriber.

3) The pharmacist-in-charge shall maintain or have access to the following records for at least 5 years or as otherwise required by law:

A) Records of medication orders and medication administration to patients;

B) Procurement records for controlled substances;

C) Records of packaging, bulk compounding or manufacturing; and

D) Records of actions taken pursuant to drug recalls.

c) Labeling Requirements

1) All medication repackaged by the pharmacy for future use inside the institution or facility and not intended for immediate dispensing to a specific patient shall be identified as follows:

A) Single dose or multi-dose drugs, except sterile solutions to which a drug has been added, shall be labeled with:

i) Brand and/or generic name;

ii) Strength (if applicable);

iii) Beyond use date; and

iv) Reference code to identify source and lot number.

B) Sterile solutions to which drugs have been added shall contain on the outer label:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added;

iii) Beyond use date and time of the admixture; and

iv) Reference code to identify source and lot number of drugs added.

2) All medication prepared by the pharmacy for immediate dispensing to a specific patient or resident in the institution or facility shall be identified as follows:

A) Single dose or multi-dose drugs, except parenteral solutions to which a drug has been added, shall be identified with:

i) Brand and/or generic name; and

ii) Strength (if applicable).

B) Sterile solutions to which drugs have been added shall be identified with:

i) Name, concentration and volume of the base sterile solution;

ii) Name and strength of drugs added; and

iii) Beyond use date and time of the admixture.

C) All medication dispensed to a specific patient in the institution shall be dispensed in a container identified with the name of the patient and the patient's location. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

3) Labels on all medications dispensed by the pharmacy for immediate dispensing to a patient being discharged, emergency room patient and/or employee shall contain the following:

A) The name and dosage form of the drug;

B) The date filled;

C) The quantity dispensed; and

D) Directions for use.

4) Investigational new drugs, authorized by the U.S. Food and Drug Administration, shall be dispensed pursuant to a valid prescription order of the principal physician-investigator or his authorized clinician. All investigational drugs shall be stored in and dispensed from the pharmacy and shall be identified with the following information:

A) Name of drug and strength (if applicable);

B) Beyond use date;

C) Reference code to identify source and lot number;

D) A label indicating "For Investigational Use Only"; and

E) Name and location of the patient. Those institutions or facilities utilizing a unit-dose and medication cart system may identify the name of the patient and the patient's location on the outside of the bin of the medication cart, when those carts are filled by the pharmacy.

5) A pharmacist providing a copy of a prescription to an ultimate consumer for the purpose of transfer or any other purpose shall cancel the face of the original prescription and record the date the copy is issued, to whom issued, and the pharmacist's signature on the face of the original prescription. Copies of prescriptions shall be marked "For Information Purposes Only" and require prescriber authorization to fill.

d) Staffing of the Pharmacy

1) The responsibilities of the pharmacist-in-charge shall include:

A) Supervision of all the activities of all employees as they relate to the practice of pharmacy;

B) Establishment and supervision of the method and manner for storage, dispensing and safekeeping of pharmaceuticals in all areas of the institution or facility, including maintenance of security provisions to be used when the pharmacy is closed. The following security provisions shall be utilized:

i) The pharmacy shall be staffed at all times by a registered pharmacist during open hours; and

ii) Only registrants and licensees shall have access to the pharmacy, except as provided in Section 1330.530(e)(1);

C) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs;

D) The development and implementation of a procedure to be utilized in the event of a drug recall that can be readily activated to assure

that all drugs included on the recall are returned to the pharmacy for proper disposition;

E) Establishment of specifications for the procurement of all drugs that will be dispensed by the pharmacy; and

F) Establishment and supervision of a method of documenting an oral prescription from a licensed physician to a pharmacist and for transmission of that information to the appropriate members of the nursing staff of the institution or facility.

2) The operations of the pharmacy and the maintenance of security provisions are the responsibility of the pharmacist-in-charge whether the owner is a sole proprietor, partnership, association, corporation or any other entity.

3) Within 30 days after the change of a pharmacist-in-charge, the Division shall be notified in writing by the departing pharmacist-in-charge.

4) The departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:

A) All Schedule II drugs, as defined in the Illinois Controlled Substances Act, by actual physical count; and

B) All other scheduled drugs, as defined in the Illinois Controlled Substances Act, by estimated count.

5) The inventory shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion and preservation of the inventory record bearing the date of the inventory and the signatures of the departing and incoming pharmacist-in-charge shall be submitted to the Division, at its principal office, within 30 days after the change in the pharmacist-in-charge.

6) Failure on the part of a registrant to provide the affidavit required in subsections (d)(4) and (5) shall be grounds for denying an application or renewal application for a pharmacy license or for disciplinary action against a registrant. Denial shall be based on the recommendation of the Board.

7) In the event the departing pharmacist-in-charge refuses to complete the inventory as provided for in subsection (d)(4), or that pharmacist-in-charge is incapacitated or deceased, the initial inventory for the incoming pharmacist-in-charge shall be the inventory as completed by the incoming pharmacist-in-charge. The incoming pharmacist-in-charge will not be responsible for any discrepancy that may exist in the inventory prior to his or her initial inventory.

8) When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

A) Provide information as may be necessary; and/or

B) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given or clear up any discrepancies or conflicts in information.

9) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale dispensed medications, chemicals, poisons or medical devices, except for:

A) Medical devices that can be properly sanitized prior to reuse, resale or re-rent; and

B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopoeia/National Formulary published by the United States Pharmacopoeial Convention, Inc.

e) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:

1) An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the

absence of a pharmacist. When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.

2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid physician's order of a physician licensed to practice medicine in all of its branches in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at such time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.

3) Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the physician's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.

4) Drugs may be dispensed from the emergency room only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution. This shall occur only during hours in which outpatient institutional pharmacy services are not available. The quantity dispensed should be limited to no more than a 72 hour supply, except for antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic, otics, etc.), to meet the immediate needs of the patient until pharmacy services are available. Drugs dispensed in this manner must meet all labeling requirements pertaining to community pharmacies as specified in Section 1330.500. There shall be written policies and procedures, approved by the medical staff, regarding the dispensing of drugs from the emergency room.

f) Pharmacies that compound and dispense sterile products shall comply with Section 1330.640.

g) Pharmacies that utilize automated dispensing and storage systems shall comply with Section 1330.680.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART F: PHARMACY STANDARDS

Section 1330.610 Pharmacy Structural/Equipment Standards

All pharmacies must comply with the following provisions:

a) Notification shall be submitted to the Division that an existing pharmacy will be remodeled.

b) Other than on-site institutional pharmacies, all dispensing, and drug storage areas of the pharmacy must be contiguous and have a connecting door for access between the pharmacy and drug storage area.

c) The pharmacy area and all store rooms shall be well-lighted and properly ventilated.

d) Refrigerators shall be for the exclusive use of prescription drugs. No personal or food items shall be stored in the refrigerator. Refrigeration shall be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing.

e) The pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy.

f) Suitable current reference sources, either in book or electronic data form (available in the pharmacy or on-line), which shall include Facts and Comparisons (http://www.factsandcomparisons.com) or other suitable references determined by the Division to be pertinent to the practice carried on in the licensed pharmacy.

g) A telephone shall be immediately accessible in the pharmacy area.

h) These requirements are in addition to any other requirements found in this Part.

i) At a minimum, the equipment and references listed in Section 1330.640 must be maintained at all dispensing pharmacies.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

SUBPART G: PHARMACY OPERATIONS

Section 1330.700 Patient Counseling

a) Upon receipt of a new or refill prescription, a prospective drug regimen review or drug utilization evaluation shall be performed. Prior to dispensing a prescription to a new patient, a new prescription~~medication~~ to an existing patient, or a medication that has had a change in the dose, strength, route of administration or directions for use, the pharmacist, or a student pharmacist directed and supervised by the pharmacist, shall provide verbal counseling to the patient or patient's agent on pertinent medication information. An offer to counsel shall be made on all other prescriptions. Counseling shall include, but is not limited to:

1) Name and description of medication;

2) Dosage form and dosage;

3) Route of administration;

4) Duration of therapy;

5) Techniques for self-monitoring;

6) Proper storage;

7) Refill information;

8) Actions to be taken in cases of missed doses;

9) Special directions and precautions for preparation, administration and use;

10) Common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.

b) If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service.

c) Every licensed pharmacy directly serving patients at a physical location must conspicuously post a sign provided by the Division containing a statement that the patient has the right to counseling, the Division's consumer hotline number, information on how to file a complaint for failure to counsel, and any other information the Division deems appropriate. The sign must be printed in color ink or displayed electronically in color, measure at least 8½ x 11 inches in size, and be posted at either a cashier counter or waiting area clearly visible to patients. Licensed pharmacies that do not maintain a physical location directly serving patients must include a copy of the sign within any dispensed prescriptions. The sign will be available to download on the Division's website.

d) The pharmacist is responsible for maintaining patient profiles as defined in Section 3(s) of the Act. A reasonable effort shall be made to obtain information, including, but not limited to, the following:

1) Name, date of birth (age), gender, address and telephone number;

2) Individual history, when significant, including disease state, known allergies, drug interactions, and a comprehensive list of medications and relevant devices; and

3) Pharmacist's comments relevant to the individual's therapy.

e) Patient identifiable information obtained by the pharmacist or the pharmacist's designee for the purpose of patient record maintenance, prospective drug review, drug utilization review and patient counseling shall be considered protected health information, as defined in Section 3(cc) of the Act. A pharmacist shall provide

counseling related to protected health information in a discreet, supportive and informative manner.

f) A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling as required in this Section unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution.

g) Nothing in this Section shall be construed as requiring a pharmacist to provide counseling when a patient or patient's agent refuses such counseling. When a patient or patient's agent refuses to accept patient counseling as provided in this Section, that refusal shall be documented.

h) A pharmacist operating a remote pharmacy shall comply with the requirements of this Section. Counseling in those circumstances shall be done by both video and audio means.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.720 Transfer of Prescription

a) A prescription may be transferred between pharmacies for the purpose of original fill or refill dispensing, provided that:

1) The transfer of~~pharmacist transferring~~ the prescription invalidates the original prescription on file and records from~~to~~ which pharmacy the prescription was transferred, the date of issuance of the copy and the name of the pharmacist, student pharmacist or pharmacy technician issuing the transferred prescription order; and

2) The pharmacist, student pharmacist, or pharmacy technician receiving the transferred prescription directly from the other pharmacy~~pharmacist~~ records the following:

A) The name, address and original prescription number of the pharmacy from which the prescription was transferred;

B) All information constituting a prescription order, including the following: name of the drug, original amount dispensed, date of original issuance of the prescription, and number of valid refills remaining; and

C) The pharmacist, student pharmacist, or pharmacy technician receiving the transferred prescription informs the patient that the

original prescription has been cancelled at the pharmacy from which it has been transferred.

b) A prescription for Schedule III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of original fill or refill dispensing and may not be transferred further. However, a pharmacist who is electronically sharing real-time on-line computerized systems may transfer up to the maximum refills permitted by law and the prescriber's authorization in accordance with CFR 1306.26(a).

c) Computerized systems must satisfy all information requirements of this Section, including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership. If those systems that access the same prescription records have the capability of cancelling the original prescription, pharmacies using such a system are exempt from the requirements of this subsection if the transferred prescription can always be tracked to the original prescription order from the prescribing practitioner and the original prescription can be produced.

d) When prescription information is transferred to another pharmacy for the purposes of original fill, the transferring pharmacy must enter a prescription into its system as if that prescription were filled at that pharmacy.

e) Nothing in this Section shall apply to transactions described in Section 20 of the Act.

f) A prescription shall only be transferred upon the request or authorization of the person for whom the prescription was issued, except upon closure of a pharmacy, in which case notice shall be made to that person, orally or in writing, of the closure and the location where the prescription is transferred.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.760 Electronic Transmission of Prescriptions

Electronic transmission of prescriptions shall be allowed, provided the following conditions are met:

a) The prescription shall be transmitted directly, or through an intermediary, from the authorized licensed prescriber to the pharmacy of the patient's choice. No intermediary shall alter the prescription information or content of the prescription.

b) The prescriptions shall comply with all applicable statutes and rules regarding the

form, content, record keeping and processing of a prescription drug.

c) The electronically transmitted prescription shall include the following:

1) The transmitting prescriber's facsimile number, if applicable;

2) The time and date of the transmission;

3) The identity of the person sending the prescription;

4) The address and contact information of the person transmitting the prescription.

d) The electronic device in the pharmacy that receives the electronically transmitted prescription shall be located within the pharmacy area.

e) The pharmacy has procedures in place for the cancellation of electronically transmitted prescriptions including the following:

1) A pharmacy using the National Council for Prescription Drug Program's SCRIPT standard for receiving electronic prescriptions must enable, activate, and maintain the ability to receive transmissions of electronic prescription cancellations and to transmit cancellation response transactions.

2) As soon as possible after the receipt of a prescription cancellation notification, but within two business days, pharmacy staff must either review the cancellation transaction to ensure that the prescription has been deactivated or ensure that deactivation occurred automatically.

3) Policies and procedures to ensure that the discontinued medications are not dispensed to a patient by a pharmacist.

f~~e~~) A facsimile of an electronically transmitted prescription shall be non-fading and remain legible.

g~~f~~) The facsimile of the electronically transmitted prescription shall be stored in the pharmacy as required by State and federal laws or rules and may serve as the record of the prescription.

h~~g~~) The electronically transmitted prescription shall serve as the record of the prescription so long as the electronically submitted prescription can be stored and is readily retrievable so as to comply with federal and State record keeping

requirements.

i~~h~~) To maintain confidentiality, adequate security and systems safeguards designed to prevent and detect unauthorized access, modification or manipulation of electronically transmitted prescriptions is required.

j~~i~~) A pharmacy or pharmacist shall not enter into an agreement with a practitioner or healthcare facility concerning the provision of any means for the electronic transmission of prescriptions that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice.

k~~j~~) Electronically transmitted prescriptions for controlled substances may be dispensed only as provided by federal law.

(Source: Amended at 47 Ill. Reg. _____, effective _____)

Section 1330.765 Requirements for Enrollment in Automated Prescription Refill Programs

Pharmacies providing automated prescription refills, whether prescribed through electronic or paper prescriptions as provided in Section 22c(a) of the Act, must:

a) Require that the patient or patient's agent agree to be enrolled in the automated refill program for each prescription medication that the patient has been prescribed.

b) Ensure that only prescriptions which include an instruction from the prescribing health care provider that the medication can be refilled be eligible for the pharmacy's automatic refill program.

c) Require that the patient or the patient's agent sign a statement that they consent to the enrollment in an automated prescription refill program for each medication for which they enroll.

d) Maintain a record of the patient's or the patient's agent's signatures showing that they consented to be enrolled in the automated refill program for each prescription in which they are enrolled.

e) Maintain policies and procedures which require that upon the pharmacy's receipt of a notice that the medication has been discontinued, the pharmacy staff take prompt action to ensure that discontinued medications are not dispensed to the patient under the automated refill program and that the patient's medication is removed from enrollment in the automated refill program.

(Source: Added at 47 Ill. Reg. _____, effective _____)

Section 1330.780 Changes~~Change~~ of Ownership, Name, Location, or Operations of a Pharmacy

a) A ~~new~~ pharmacy application must be filed whenever any of the following occur:

1) 50%~~10%~~ or more of the ownership of the business, other than a publicly traded business, to which the pharmacy license~~licensee~~ was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the pharmacy license prior to the sale or transfer; ~~or~~

2) More than half the board of directors or executive officers of a business issued a pharmacy license changes;~~change.~~

3) Any change in the legal status of an entity;

4) Any change in location of a pharmacy, including remodel of the pharmacy or drug storage area;

5) Any change in the name of a pharmacy; or

6) Any change in the pharmacy operations pursuant to Subpart E of this Part or the Act.

b) Any change of ownership of a parent company that owns a pharmacy shall not be considered a change of ownership of the pharmacy.

c) The application required by subsection (a) must be filed:

1) At least 90 days prior to occurrence of the change requiring the application for pharmacies located in Illinois.

2) No later than 30 days after the occurrence of the change requiring the application for pharmacies located outside of Illinois.

d) The Division must be notified no later than 30 days after any change in owners, partners, members, officers, directors, or shareholders owning 5% or more of the outstanding shares occurs, or any other change in the information provided on the application not specified in subsection (a).

(Source: Amended at 47 Ill. Reg. _____, effective _____)